UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

WILLIAM PLOURDE, *Individually and as Administrator of the Estate of Allison Plourde*, and FREDA MERRILL,	*	
Plaintiffs,	*	
v.	*	Civil Action No. 17-cv-10507-ADB
SORIN GROUP USA, INC. and CARBOMEDICS, INC.,	*	
Defendants.	*	

MEMORANDUM AND ORDER ON MOTION TO DISMISS

BURROUGHS, D.J.

Plaintiffs William Plourde and Freda Merrill are the parents of Allison Plourde, who died in February 2014 after suffering complications during a surgery to remove an aortic bioprosthetic heart valve, the Sorin Mitroflow Aortic Pericardial Heart Valve (the "Valve"). Defendant Sorin Group USA, Inc. manufactures and sells the Valve.[1] Plaintiffs bring claims based on Massachusetts state law for breach of warranty, negligence, failure to warn, and a violation of the consumer protection statute, Mass. Gen. Laws ch. 93A. [ECF No. 1-1 at 17–30]. Now before the Court is Defendants' motion to dismiss for failure to state a claim [ECF No. 16], which asserts that all of Plaintiffs' claims are preempted by federal law. For the reasons set forth below, the motion is granted in part and denied in part.

I. BACKGROUND

The following facts are drawn from the complaint, the allegations of which are taken as

[1] CarboMedics, Inc. is also named as a defendant. Defendants assert that CarboMedics was merged into Sorin Group USA, Inc. in January 2010, and thus no longer exists as a legal entity which can sue or be sued. [ECF No. 17 at 1 n.1].

true for purposes of evaluating the motion to dismiss. Ruivo v. Wells Fargo Bank, 766 F.3d 87, 90 (1st Cir. 2014).

A. Allison Plourde

Allison Plourde, a resident of Massena, New York, was born with DiGeorge syndrome and later diagnosed with aortic arch and ventricular septal defect. She received ongoing treatment for 21 years, and lived a normal life given her diagnosis. On June 19, 2012, Ms. Plourde underwent an aortic heart valve replacement surgery at Boston Children's Hospital ("BCH") during which the Valve was implanted in her heart. The Valve contained bovine animal tissue and did not contain any anti-calcification reduction treatment. After the implant surgery, Ms. Plourde continued to meet with her doctor for regular follow-up treatment.

In January 2014, physicians at BCH conducted an autopsy of a recently deceased 13-year-old girl who had also received an implanted Valve. The autopsy revealed that the girl's Valve had severely deteriorated, despite the fact that she had an echocardiogram seven months earlier which showed only mild stenosis and decreased leaflet mobility. This caused BCH physicians to become concerned that, given the deterioration, patients might not be receiving heart valve related check-ups frequently enough to detect deterioration before it became life-threatening. The BCH physicians concluded that the increased metabolism and blood flow common in patients under 30 years old caused a heightened risk of bovine tissue deterioration in the Valve, which necessitates a risky second surgery, and in some cases proves fatal.

In mid-January, 2014, BCH physicians called BCH patients who had recently received a Valve implant and requested that they be immediately evaluated to determine whether their implants showed signs of premature rapid deterioration. Ms. Plourde received a phone call from a BCH physician on January 13, 2014 requesting that she immediately be examined to determine

whether her Valve had experienced rapid deterioration. Ms. Plourde was admitted to BCH on January 14, 2014. Testing revealed that her Valve was so severely deteriorated that it required immediate removal and replacement with a valve from a different manufacturer. Ms. Plourde underwent valve replacement surgery on January 16, 2014. During the surgery, she experienced severe complications due to the calcification of the Valve leaflets. Upon removal of the Valve, the calcified heart valve leaflets broke off, leading to hemorrhaging and chest wall bleeding. Ms. Plourde was transferred to the Intensive Care Unit, where she remained in a coma until February 7, 2014, when she was taken off life support and pronounced dead.

In April 2014, BCH physicians published a study in a scientific journal, Circulation, which concluded that patients under 30 who received the Valve were at heightened risk for rapid progression from mild to severe aortic stenosis over the course of months. The study determined that "heightened echocardiographic surveillance" was required, and suggested that the Valve should not be implanted in young patients. Ms. Plourde was one of the patients referenced in this study.

B. The Valve

The U.S. Food and Drug Administration ("FDA") issued premarket approval allowing the Valve to be sold on the market on October 23, 2007.[2] The premarket approval required the Valve to be sold with a warning that it carried a heightened risk of deterioration in patients younger than 55.

Plaintiffs assert that Defendants learned between October 23, 2007 and the date the Valve was installed in Ms. Plourde, June 19, 2012, that the Valve had a heightened propensity for valve

[2] The complaint contains allegations that Defendants were aware of the potential for early deterioration in patients under 30, but did not fully inform the FDA of these issues during the premarket approval process. For the reasons discussed infra, however, these allegations are not relevant to the pending motion to dismiss.

calcification and deterioration in individuals younger than 30, above and beyond the risks disclosed to the FDA in its original premarket approval application. Plaintiffs claim that Defendants knew or should have known of studies conducted in several countries which indicated that the Valve experienced rapid premature deterioration and calcification in patients under 30 years old, necessitating check-ups more frequently than originally recommended. Plaintiffs further contend that Defendants did not update the FDA with information concerning the calcification problem or the rapid premature deterioration in recipients under 30 years old prior to June 19, 2012. They assert that, had Defendants kept the FDA informed of these issues, the FDA could have issued a more particularized warning describing the risks involved in installing the Valve in patients younger than 30, thus preventing Ms. Plourde's death.

Following the 2014 publication of the study by the BCH physicians, Defendants addressed the Valve's rapid deterioration problem by implementing anti-calcification measures known as Phospholipid Reduction Treatment.

II. DISCUSSION

A. Standard of Review

To withstand a motion to dismiss under Rule 12(b)(6), a complaint must allege a claim for relief that is "plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). Assessing the plausibility of a claim is a two-step process. "First, the court must sift through the averments in the complaint, separating conclusory legal allegations (which may be disregarded) from allegations of fact (which must be credited). Second, the court must consider whether the winnowed residue of factual allegations gives rise to a plausible claim to relief." Rodriguez-Reyes v. Molina-Rodriguez, 711 F.3d 49, 53 (1st Cir. 2013) (citation omitted). Along with all well-pleaded facts, the Court must draw all logical inferences from a complaint in favor of the

plaintiff. Frappier v. Countrywide Home Loans, Inc., 750 F.3d 91, 96 (1st Cir. 2014). "If the factual allegations in the complaint are too meager, vague, or conclusory to remove the possibility of relief from the realm of mere conjecture, the complaint is open to dismissal." Rodriguez-Reyes, 711 F.3d at 53 (quoting SEC v. Tambone, 597 F.3d 436, 442 (1st Cir. 2010) (en banc)).

B. Preemption

In 1976, Congress enacted the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"), to require FDA approval before new medical devices are introduced into the market. Riegel v. Medtronic, Inc., 552 U.S. 312, 315 (2008). This "new regulatory regime established various levels of oversight for medical devices, depending on the risks they present." Id. at 316. Class I devices are subject to the lowest level of federal scrutiny, while Class III devices receive the greatest oversight. Id. at 316–17. To obtain permission to sell a new Class III device, a manufacturer must go through the premarket approval process, which is "rigorous." Id. at 317. The manufacturer must ordinarily submit a "multivolume application," and the FDA spends an average of 1,200 hours reviewing each submission to evaluate the device's safety and effectiveness. Id. at 317–18. "Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." Id. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). "After premarket approval, the devices are subject to reporting requirements," including

> the obligation to inform the FDA of new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know of, and to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred.

Id. at 319 (citing 21 U.S.C. § 360i and 21 C.F.R. §§ 803.50(a), 814.84(b)(2)).

Prior to the enactment of the MDA, several states had adopted their own measures to regulate the sale of medical devices. Id. at 315–16. The MDA contains an express preemption provision, however, which provides that:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

The Supreme Court has decided a few key cases concerning preemption as relevant here. In Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 343 (2001), the plaintiffs attempted to bring a state tort claim alleging that the defendant device manufacturer made fraudulent representations to the FDA during the premarket approval process, and that the device at issue would not have been approved but for defendant's fraud. The Court held that the "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law." Id. at 348. It went on to explain that "the federal statutory scheme amply empowers the FDA to punish and deter fraud against" the agency, and the FDA uses this authority "to achieve a somewhat delicate balance of statutory objectives," which "can be skewed by allowing fraud-on-the-FDA claims under state tort law." Id.

Next, in Riegel, the plaintiffs sued a device manufacturer, alleging that a device which had received Class III approval from the FDA was defective under state law. Riegel, 552 U.S. at 320. The Court determined that the claims were expressly pre-empted because state law imposed a more stringent safety standard than federal law. Id. at 325. The Court went on to explain,

however, that because "[s]tate requirements are pre-empted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law," the preemption provision of the MDA "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." Id. at 330 (quoting 21 U.S.C. § 360k(a)(1) and Medtronic, Inc. v. Lohr, 518 U.S. 470, 495 (1996)); see also Lohr, 518 U.S. at 495 ("Nothing in § 360k denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements.").

Thus, read together, "Riegel and Buckman create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption." In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig., 623 F.3d 1200, 1204 (8th Cir. 2010) (quoting Riley v. Cordis Corp., 625 F. Supp. 2d 769, 777 (D. Minn. 2009)). To fit through this gap, "[t]he plaintiff must be suing for conduct that *violates* the FDCA (or else his [or her] claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA ([as] such a claim would be impliedly preempted under Buckman)." Id. (quoting Riley, 625 F. Supp. 2d at 777).

Defendants contend in their motion to dismiss that all of Plaintiffs' claims are preempted. In their opposition, Plaintiffs argue only that their claims for failure to report new information to the FDA after the Valve was approved are not preempted. As such, Plaintiffs implicitly concede that the claims relating to events occurring during the premarket approval process are preempted, and therefore, the motion to dismiss those claims is granted.[3]

[3] The Court agrees that claims alleging malfeasance during the premarket approval process are preempted. See Buckman, 531 U.S. at 343, 348 (state-law claim asserting manufacturer made fraudulent representations to FDA is preempted).

Plaintiffs assert that their claims for failure to report new information to the FDA after the Valve was approved are parallel claims that fit within the "narrow gap" of claims that are not preempted, as defined by Riegel and Buckman. In particular, these claims assert that state law imposed a duty on Defendants to report new scientific studies and incidents in which the device contributed to serious injury or death to the FDA. There are no directly applicable First Circuit cases, but several other federal courts have considered this issue. Most courts have concluded that, as long as state law provides an independent cause of action for failure to report information to the FDA, such a claim is not preempted by federal law.

In Stengel v. Medtronic Inc., 704 F.3d 1224, 1232 (9th Cir. 2013) (en banc), the Ninth Circuit considered whether preemption barred a claim that the defendant had a continuing duty under federal law to "monitor the product after pre-market approval and to discover and report to the FDA any complaints about the product's performance and any adverse health consequences," and that by failing to comply with federal law, "it breached its duty to use reasonable care under Arizona negligence law." The court began by explaining that the "[t]he rule that emerges from [Lohr, Buckman, and Riegel] is that the MDA does not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty under the MDA." Id. at 1228. The particular claim at issue in Stengel "specifically allege[d], as a violation of Arizona law, a failure to warn the FDA," and the court found that "Arizona law contemplates a warning to a third party such as the FDA." Id. at 1233. The court then determined that the Arizona law claim, "insofar as the state-law duty parallels a federal-law duty under the MDA, is not preempted." Id. It noted that the Fifth and Seventh Circuits had reached the same conclusion in Hughes v. Boston Science Corp., 631 F.3d 762, 765 (5th Cir. 2011) and Bausch v. Stryker Corp., 630 F.3d 546, 558 (7th Cir. 2010), respectively. Stengel, 704 F.3d at 1232. Next, the court distinguished Sprint Fidelis, 623

F.3d at 1203, in which the Eighth Circuit held that state law claims for, inter alia, defective design and manufacturing were preempted by the MDA. Id. In the court's view, Sprint Fidelis was different for two reasons: "First, plaintiffs sought to enforce state-law requirements that would have required [the manufacturer] 'to give additional warnings, precisely the type of state requirement that is different from or in addition to the federal requirement.'" Id. (quoting Sprint Fidelis, 623 F.3d at 1205). "Second, the [Sprint Fidelis] plaintiffs sought to bring actions based solely on the MDA rather than on state law, which the court found foreclosed by Buckman." Id. Here, Plaintiffs' claims are more like those in Stengel than Sprint Fidelis: the claims are based on state law, and do not seek to impose additional requirements beyond what is required by federal law.

In Hughes, one of the cases the Ninth Circuit relied on in Stengel, the plaintiff asserted claims "under the Mississippi tort law theories of products liability, breach of warranty, negligence, breach of implied warranty of merchantability, and of fitness for a particular purpose." 631 F.3d at 765. In part, the plaintiff alleged that the device did not contain adequate warnings, but the court determined that all of the "state products liability claims that purport to impose liability on [the manufacturer] despite [the manufacturer]'s compliance with the applicable FDA design and manufacturing specifications," including the claim for failure to provide adequate warnings, were expressly preempted. Id. at 768–69. The court went on to find, however, that "to the extent [the plaintiff] asserts that [the manufacturer] violated the state duty to warn by failing to accurately report serious injuries and malfunctions of the [device] as required by the FDA's [Medical Device Reporting] regulations," such a claim was not preempted. Id. at 770. The court reasoned that a factfinder could determine that a violation of the federal regulations requiring the manufacturer to report new information to the FDA "is a

parallel violation of the state duty to provide reasonable and adequate information about a device's risks." Id. at 770–71.

In Bausch, 630 F.3d at 549, the plaintiff brought state-law claims for negligence and products liability based on the allegation that the device in question was defective and not manufactured according to federal standards. The Seventh Circuit explained that the MDA preemption provision "protects a medical device manufacturer from liability to the extent that it has *complied* with federal law, but it does not extend protection from liability where the claim is based on a *violation* of federal law," or, "[i]n other words, where state law is parallel to federal law, [the MDA preemption provision] does not preempt the claim." Id. at 552. Thus, the court determined that if the plaintiff "can prove those allegations of harm caused by violations of federal law, her claims under state law would not impose on defendants any requirement 'different from, or in addition to, any requirement' imposed by federal law," and so the claims were not preempted. Id. at 553 (quoting 21 U.S.C. § 360k(a)).

Many federal district courts outside of the Fifth, Seventh, and Ninth Circuits have reached the same conclusion, expressly relying on Stengel, Hughes, and Bausch. See, e.g., McLaughlin v. Bayer Corp., 172 F. Supp. 3d 804, 836–38 (E.D. Pa. 2016) (claims based on Pennsylvania state tort law alleging that defendant failed to report post-approval information to FDA not preempted); Williams v. Smith & Nephew, Inc., 123 F. Supp. 3d 733, 742–43, 746 (D. Md. 2015) (same, based on Maryland law); Rosen v. St. Jude Med., Inc., 41 F. Supp. 3d 170, 185 (N.D.N.Y. 2014) (same, based on New York law); Waltenburg v. St. Jude Med., Inc., 33 F. Supp. 3d 818, 838–40 (W.D. Ky. 2014) (same, based on Kentucky law); Kubicki ex rel. Kubicki v. Medtronic, No. CIV.A. 12-00734 CKK, 2013 WL 1739580, at *6–9 (D.D.C. Mar. 21, 2013)

(same, based on District of Columbia law).[4]

In most cases where courts have disagreed with Stengel, Hughes, and Bausch, and found that a state law claim for failure to report post-approval information to the FDA was preempted, the reasoning turned on the fact that the particular state law at issue did not impose a duty on the manufacturer to report this information to the FDA. See, e.g., Aaron v. Medtronic, Inc., 209 F. Supp. 3d 994, 1004–06 (S.D. Ohio 2016) (finding state law failure to warn claim preempted because Ohio law requires manufacturers to warn patients or physicians, but not the FDA, and thus state law duty is not parallel to federal requirements); Pearsall v. Medtronics, Inc., 147 F. Supp. 3d 188, 200–01 (E.D.N.Y. 2015) (state law failure to warn claim preempted because New York law requirement that manufacturers warn the medical profession "is not the same as a duty to report to the FDA," and disagreeing with Rosen that New York law imposes duty to warn FDA identical to federal law); Pinsonneault v. St. Jude Med., Inc., 953 F. Supp. 2d 1006, 1015 (D. Minn. 2013) (finding state law duty to warn claim preempted where plaintiffs could not identify state law that imposed duty to warn FDA, rather than patients and doctors).

In their reply brief, Defendants rely on a Massachusetts Superior Court opinion which explained that "[n]umerous courts have concluded that claims based on a manufacturer's failure to report to the FDA or notify it of adverse events are impliedly preempted under" the MDA. Phillips v. Medtronic, Inc., No. SUCV2009-05286-A, 2012 WL 3641487, slip op. at 20 (Mass. Super. Ct. July 10, 2012). Thus, the court

[4] In addition, Plaintiffs cite to a Massachusetts Superior Court decision which held that "a claim that the manufacturer failed to warn the FDA of adverse events associated with particular off-label uses" would survive preemption as long as Massachusetts law recognized such a claim. Scoggins v. Bos. Sci. Corp., No. 07-4049, 2010 WL 8911977, slip op. at 28–29 (Mass. Super. Ct. Oct. 18, 2010). While Scoggins concerned the off-label use of a device, it nonetheless supports Plaintiffs' position that a state-law claim for failure to report information to the FDA is not preempted. The court did not analyze whether a claim for failure to report information to the FDA was cognizable under Massachusetts law. Id.

> reluctantly conclud[ed] that a parallel claim based on failure to report adverse events, corrections and removals, and failure to submit supplemental reports to the FDA is impliedly preempted because it is premised solely on a duty created by the MDA which did not exist in the common law: the duty to provide information to a regulatory agency to enable it to determine whether to take enforcement action with respect to a device approved through the [premarket approval] process.

Id. at 21. This Court disagrees with the Phillips court's assessment of the law. In support of its holding, the Phillips court cited several cases, but these cases do not provide the most useful guidance here. For example, the court cited an earlier opinion of the Ninth Circuit in Stengel v. Medtronic Inc., 676 F.3d 1159, 1164 (9th Cir. 2012), but that decision was reversed by the en banc opinion discussed supra, 704 F.3d 1224 (9th Cir. 2013), which was decided the year after the Phillips opinion was issued. The Phillips court also cited Gomez v. St. Jude Medical Daig Division Inc., 442 F.3d 919, 931 (5th Cir. 2006). Five years after Gomez was decided, the Fifth Circuit in Hughes discussed Gomez and relied on it in holding that a state-law claim for a violation of the duty to warn due to the failure to inform the FDA of injuries and malfunctions was not preempted. Hughes, 631 F.3d at 770. In addition, the Phillips court cited Cenac v. Hubbell, No. CIV.A. 09-3686, 2010 WL 4174573, at *6 (E.D. La. Oct. 21, 2010), which relied on Gomez, and predated Hughes.

The Phillips court also cited Riley v. Cordis Corp., 625 F. Supp. 2d 769, 790 (D. Minn. 2009), in which the plaintiff attempted to bring a state-law claim for "failure to follow the conditions" of the device's premarket approval issued by the FDA. The Riley court reasoned that "it is nonsensical to speak of a state-law claim for 'failure to follow the conditions of the [premarket approval]' in the absence of the federal regulatory structure that provides for that [premarket approval]," and thus, such a claim was preempted. Id. Additionally, the court noted that because the device was implanted in plaintiff only a week after it received approval, there was no new information to report. Id. Here, on the other hand, Plaintiffs' claims are not premised

on a failure to comply with the terms of the premarket approval, but rather, are based on the state-law duty to report new studies and post-approval injuries to the FDA. Similarly, in In re Medtronic, Inc. Sprint Fidelis Leads Product Liability Litigation, 592 F. Supp. 2d 1147, 1160–61 (D. Minn. 2009), also cited in Phillips, the court held that the plaintiff could not bring a claim for a violation of the FDCA, because the FDCA does not supply a private cause of action. The court further held that the plaintiffs "cannot make an end run around this rule by recasting violations of the FDCA as violations of state common law." In Sprint Fidelis, however, it appears that the substance of these contemplated state law claims was only that defendant had violated federal law. Id. at 1161 (stating that plaintiffs had described the claims as "state-law claims for violations of the FDCA," with no further elaboration). Thus, the court did not discuss whether state law imposed an independent duty to submit information to the FDA. Id. Lastly, the Phillips court cited McGuan v. Endovascular Technologies., Inc., 182 Cal. App. 4th 974, 984 (2010), which determined that fraud and misrepresentation claims for failure to report information were preempted, because such claims essentially amounted to fraud-on-the-FDA. Here, however, Plaintiffs' claims do not include fraud or misrepresentation.

For the reasons discussed supra, the Court concludes that Stengel, Hughes, and Bausch provide better guidance than the cases cited in Phillips, and thus it concurs with the many federal district courts which have determined that a state-law claim for failure to report information to the FDA is not preempted. See, e.g., McLaughlin, 172 F. Supp. 3d at 836–38; Williams, 123 F. Supp. 3d at 742–43; Waltenburg, 33 F. Supp. 3d at 838–40.

Defendants also point out that the Phillips court held that, in general, the duty to report information to the FDA was not one that existed at common law. Phillips, No. SUCV2009-05286-A, slip op. at 21–22. In explaining its reasoning, however, the court did not discuss

Massachusetts law or cite any Massachusetts cases. Cases like Stengel and Hughes make clear that the preemption analysis in this area turns on whether a particular state's common law requires the manufacturer to report information to the FDA, see Stengel, 704 F.3d at 1233, and Hughes, 631 F.3d at 775, because some states do not impose such a requirement, see, e.g., Aaron, 209 F. Supp. 3d at 1004–1006. The Phillips court, however, did not specifically examine whether this duty exists under Massachusetts common law. Instead, in support of its conclusion, the court cited only Buckman for the proposition that a claim for *pre-approval* fraud on the FDA was preempted, and the earlier decision in Stengel which was later overturned by the court sitting en banc. Phillips, No. SUCV2009-05286-A, slip op. at 21–22 (citing Buckman, 531 U.S. at 350–52, and Stengel, 676 F.3d at 1164). Thus, the Phillips court's determination on this issue is not persuasive, especially given the developments in the caselaw that occurred after Phillips was decided.

Defendants cite two additional cases in support of their position, but those cases are clearly distinguishable. In Byrnes v. Small, 60 F. Supp. 3d 1289, 1297 (M.D. Fla. 2015), the Court held that the plaintiff had "failed to identify any Florida state law duty to report" adverse events to the FDA, so the state law claim for failure to warn was preempted. Thus, this case is similar to those discussed supra which concluded that claims were preempted because the state law at issue did not impose a duty to provide information to the FDA. Next, in Lake v. Kardjian, 874 N.Y.S.2d 751, 755 (Sup. Ct. 2008), the court held that the plaintiff could not bring a claim based on federal law, because federal law does not provide a private cause of action, and such claims are preempted. In dicta, the court went on to explain that even if the plaintiff had attempted to bring a state-law claim based on the violation of federal law, that claim would be preempted. Id. Thus, the reasoning in Lake is essentially the same as that of the District of

Minnesota Sprint Fidelis opinion: in order to survive preemption, a state law claim cannot be premised solely on a violation of federal law, but rather, must be based on an independent duty that arises from state law itself. This holding does not suggest that the claims in the present case are preempted, however, because Plaintiffs have asserted that Massachusetts common law imposes a duty to report information to the FDA which is independent of federal law, but yet which precisely tracks the requirements imposed by federal law.

Lastly, Defendants argue for the first time in their reply brief that Plaintiffs have not alleged an adequate "causal nexus" between the asserted violation of FDA regulations and the death of Ms. Plourde. Defendants advocate for the use of a test to evaluate the strength of the "causal nexus" which is apparently employed by district courts within the Ninth Circuit, without explaining why that test should be used here. That test requires the plaintiff to "allege facts (1) showing an alleged violation of FDA regulations or requirements related to the device, and (2) establishing a causal nexus between the alleged injury and the violation" in order to survive preemption. Erickson v. Bos. Sci. Corp., 846 F. Supp. 2d 1085, 1092–93 (C.D. Cal. 2011) (internal quotation marks omitted). The test apparently originated in Cohen v. Guidant Corp., No. CV-05-8070-R, 2011 WL 637472, at *1 (C.D. Cal. Feb. 15, 2011), where the court determined that "general allegations that Defendants failed to comply with federal requirements are inadequate to plead parallel claims under Riegel," and that "factual support and details" are required. In that case, the complaint "list[ed] boilerplate FDA regulations without linking any of those regulations to a defect in [the plaintiff's] specific pacemaker that was caused by [d]efendants violating FDA regulations." Id. at *2.

In contrast, here, Plaintiffs have provided detailed factual allegations showing that, between 2007 and 2012, Defendants were aware or should have been aware of studies and

incidents indicating that the Valve was more likely to calcify and rapidly deteriorate in patients under 30, such as occurred with Ms. Plourde's implanted Valve, but Defendants did not report this information to the FDA, in violation of federal regulations and state law. Plaintiffs further assert that the FDA could have required a more particularized warning concerning patients under 30 if it had been aware of this issue, and that if such a warning had been given, the Valve would not have been implanted in Ms. Plourde and its failure leading to her death would not have occurred. Defendants emphasize that the device already carried a warning covering patients under 55, but the complaint alleges that the Valve posed a unique risk to patients under 30 which was not reflected in the warning. Defendants also assert that Plaintiffs will not be able to prove that the FDA would or should have issued a particular warning, but the Court need not make such a determination on a motion to dismiss. See Rosen, 41 F. Supp. 3d at 188 (finding allegation that plaintiff's "injuries may have been avoided or mitigated had [d]efendants timely complied with" the requirement to report adverse events to FDA "is not purely contingent or speculative" (internal quotation marks omitted)); cf. Hawkins v. Medtronic, Inc., No. 1:13-CV-00499 AWI SK, 2014 WL 346622, at *8 (E.D. Cal. Jan. 30, 2014) (holding plaintiff had not demonstrated causation where the "only specific example provided in the complaint of [d]efendants' failure to report an adverse event notes that the event was ultimately reported three months after the fact," and complaint provided no dates "that might allow the inference that *timely* reporting could have affected" the use of the device during plaintiff's surgeries). Thus, even if Defendants did not waive this argument, and the Ninth Circuit causal nexus test applies here, Plaintiffs have stated sufficient factual allegations to survive the test at the motion to dismiss stage.

Thus, the Court concludes that, to the extent Plaintiffs allege that Defendants had a duty

under Massachusetts law to report studies and adverse events that occurred after the Valve received premarket approval to the FDA, those claims are not preempted. Importantly, at this time, the Court makes no determination as to whether Massachusetts law actually imposes such a duty. Defendants have not argued that Massachusetts law does not require manufacturers to report the information at issue to the FDA, aside from one line in their reply brief that states that Plaintiffs have not identified such a duty [ECF No. 25 at 5], but provides no discussion of Massachusetts law and does not cite any Massachusetts cases. Nor have Plaintiffs addressed this question, aside from asserting that the duty does exist under Massachusetts law. Thus, the issue is not properly before the Court on the present motion to dismiss. In order to prevail in this case, however, Plaintiffs will have to demonstrate at a later point in the proceedings that Massachusetts law imposes such a duty.

III. CONCLUSION

Accordingly, Defendants' motion to dismiss [ECF No. 16] is GRANTED in part and DENIED in part. All claims concerning Defendants' actions during the premarket approval process are dismissed. The motion is denied, however, as to claims based on Defendants' alleged duty to report post-approval information and incidents to the FDA.

SO ORDERED.

March 29, 2018

/s/ Allison D. Burroughs
ALLISON D. BURROUGHS
U.S. DISTRICT JUDGE